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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,668	03/30/2004	Branson W. Ritchie	UGRF123806	3574

26389 7590 05/01/2008

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,668	RITCHIE ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16 and 18-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-16 and 18-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 1/24/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9, 11-13, 15, 16, 18, 19 and 23-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Mulder (USPN 5,565,189 hereafter '189) in view of both Steel et al (USPN 6,224,853 hereafter '853) and Huber et al (USPN 3,758,682 hereafter '682). The claims are drawn to a cleansing composition comprising detergents such as cocamidopropyl betaine and a pH buffer such as Tris (hydroxymethyl) aminomethane base.

The '189 patent teaches a method of cleaning the skin comprising the application of a cleansing composition comprising a carrier, water and aloe vera gel, a pH buffer such as sodium borate, chelators such as EDTA, vitamin E surfactants such as cocamphoacetate and biocides such as hydroxyquinoline (example 1). The method further debriding the wound site, rinsing the

composition after it is applied (col. 4, lin. 45-55). The pH of the composition is between pH 6.5-6.8 (col. 4, lin. 3-10). The formulation includes sensitizers that relieve pain (example 1).

As discussed above the '189 patent discloses a cleansing composition comprising detergents (surfactants) and alkaline pH buffers (sodium borate) but does not disclose the specific compounds of the instant claims. However these compounds are well known and their inclusion is within the level of skill in the art as shown by the '853 and the '682 patents.

The '853 patent discloses an aqueous formulation comprising lanolin and further co-surfactants such as cocamidopropyl betaine and lecithin where the surfactant is present in a concentration from 1-25% (col. 4, lin. 18-39, col. 5, lin. 20-45; col. 6, lin. 40-50). It would have been obvious to include these surfactants and components into the formulation of the '189 in order to reduce the irritation to the applied area.

The '682 patent discloses a formulation useful in wound healing comprising a buffer solution comprising tris(hydroxymethyl) amino methane (col. 13, lin. 25-30). Further the composition can be administered orally contacting the oral mucosa (col. 24, lin. 19-53). The artisan of ordinary skill would have been motivated to include these components in order to improve the stability of the wound treating formulation.

Regarding the specific ranges and concentrations of the specific components, it is the position of the Examiner that such limitations do not patentability to the claims. The '189 patent though silent to the molar ratios of the buffers, chelators and active agents, the reference discloses from 0.08-0.12% of a chelating agent and up to 1% buffers in the formulation. The vitamin E concentrations are equally low. It is the position of the Examiner that the general conditions of the claims have been met. It is the position of the Examiner that the concentrations

and ratios are well within the level of skill in the art to optimize in order to arrive at the current invention and to provide a stable formulation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the specific application points of the cleansing compositions it is the position of the Examiner that the specific are of application does not impart patentability to the claims in view of the prior art. The '189 and '853 patents disclose that the cleansing formulation is applied to the skin and hair to all parts of the body (col. 6, lin. 35-50). It is the position of the Examiner that it would be obvious to an artisan of ordinary skill to apply the cleansing to any portion of the body.

With these things in mind it would have been obvious to combine the detergents and buffers of the '853 and '682 patents into the cleansing formulation of the '189 patent in order to improve the stability of the cleansing formulation. It would have been obvious to combine these compounds with an expected result of a stable cleansing composition and improve method of cleansing and disinfecting the skin at a wound site.

Claims 1, 4, 10, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder et al (USPN 5,565,189 hereafter '189) in view of Steel et al (USPN 6,224,853 hereafter '853) and Robertson et al (USPN 4,939,135 hereafter '135).

As discussed above the '189 and '853 patents provide a skin cleaning composition and method of use. The formulation comprising chelators, pH buffers, carriers, antimicrobial agents and stabilizers. The combination however is silent to the specific active agent and stabilizers of the instant claims. These compounds however are common in the art as seen in the '135 patent.

The '135 patent discloses a wound healing formulation and method of applying the formulation to an ocular injury (abstract). The formulation comprises anti-inflammatory agents such as dexamethasone and antimicrobials such as neomycin and vancomycin (col. 4, lin. 60-65; col. 9, lin. 60-68). The active agents are in a concentration from 0.5-1.0% of the total formulation (col. 8, lin. 1-5). The formulation further comprises chelators and sorbic acid (col. 10, lin. 60-65). The artisan of ordinary skill would be motivated to combine the components of the '189 patent with those of the '135 patent since they both solve the same problem of wound management with cleansing compositions.

With these things in mind it would have been obvious to combine the teachings in order to improve the efficiency of the wound treatment of the '135 patent. It would have been obvious to combine the teachings with an expected result of an improved method of treating ocular wounds.

Claims 1, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder et al (USPN 5,565,189 hereafter '189) in view of Steel et al (USPN 6,224,853 hereafter '853) and Gehlsen (USPN 6,270,781 hereafter '781). The claims are

drawn to a topical formulation comprising pH stabilizers, detergents, antimicrobial agents, colorants and perfumes.

As discussed above the '189 and '853 patents provide a skin cleaning composition and method of use. The '189 patent discloses a skin cleansing formulation comprising pH stabilizers, detergents, antimicrobial agents and other components with inherent fragrances such as aloe vera and lanolin (examples). The reference however is silent to additional perfumes and colorants. The inclusion of these components is well within the level of skill in the art as seen in the '781 patent.

The '781 patent discloses a topical skin composition comprising detergents, antimicrobial agents, perfumes and pigments (col. 8, lin. 6-15; col. 8, lin. 57-65; col. 9, lin. 28-32). The artisan of ordinary skill would have been motivated to include the pigments and perfumes of the '781 with the formulation of the '189 since they comprise similar components in the same field of endeavor.

One of ordinary skill in the art would have been motivated to combine the components of the '781 patent in to the formulation of the '189/'853 patent combination in order to improve the aesthetic properties of the cleansing formulation. It would have been obvious to combine these components with an expected result of an aesthetically pleasing fragrant skin cleansing composition.

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder et al (USPN 5,565,189 hereafter '189) in view of Steel et al (USPN 6,224,853 hereafter '853) and Horn (USPN 5,848,700 hereafter '700). The claims are drawn to a kit comprising a skin cleanser and instructions to use the cleanser.

As discussed above the '189/'853 patent combination discloses a skin cleansing formulation comprising chelators, carriers, pH buffers, a detergent and an antimicrobial agent. The reference discloses instructions of the use and application of the skin cleansing composition. The reference discloses method of applying the cleansing to the skin by is silent to a specific kit. The inclusion of a kit is well known in the art and shown in the '700 patent.

The '700 patent discloses a kit comprising instructions for various applications methods inclusion cleansing the skin of burns, cuts, wounds and fractures (claims). It would have been obvious to include the skin cleanser of the '189 with the instruction of the '700 since they both endeavor to treat wounds.

One of ordinary skill in the art would have been combine the instructions of the '700 patent with the cleanser of the '189/'853 patent combination in order to form a kit to ensure proper and safe use of the cleansing formulation. One of ordinary skill in the art would have been motivated to make the combination with an expected result of a kit comprising a skin cleansing formulation and instructions for proper and safe use that would be accessible to those of ordinary skill it the art.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9-16, and 18-43 have been considered but are moot in view of the new ground(s) of rejection. The Mulder patent continues to obviate the claims by disclosing a cleansing product comprising chelators, surfactants and biocides.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618